present application into an astonishing number of groups.

Claims which depend from claim 5 (the only independent claim the U.S. Patent and Trademark Office has indicated as being willing to examine in this application) cannot be subjected to a restriction requirement relative to claim 5–a claim and a claim which depends therefrom are, by definition, not "independent". Claims (e.g., claim 45 and claim 57) which are withdrawn from consideration in view of an election of species requirement must be examined upon a determination that a generic claim (e.g., claim 5) is found to be allowable. In addition, upon reaching the conclusion that in view of the remarks herein, claims in this application are allowable, and after consequent consideration of species within the allowable genus, the U.S. Patent and Trademark Office is urged to review the pending claims again in order to consider the claims that can readily be considered without undue additional burden.

In addition, it is again respectfully noted that the U.S. Patent and Trademark is not permitted to attempt to divide the subject matter of a generic claim on the basis of a restriction requirement or an election of species requirement. Such was specifically held in precedent which is binding on the U.S. Patent and Trademark Office in In re Weber, Soder, and Boksay, 198 USPQ 328 (CCPA 1978) and Ex parte Holt and Randell, 214 USPQ 381 (Pat. Off. Bd. App. 1982). Statements such as "claim 43 is examined only in the context of other therapeutically effective agents which are adjuvants, and not anti-inflammatory agent" ignores such precedent, and is improper under U.S. law. Withdrawal of such statements is requested.

Claims 5, 43, 44, 46 and 47 were rejected under 35 U.S.C. 112, second paragraph. The Office Action contains a statement that "PLA2", which is clearly defined in the specification as referring to phospholipase A2, must be replaced in the claims with "phospholipase A2". The applicants disagree with this rejection (as is well known, an applicant can be his own lexicographer so long as his definition is not repugnant to classification), but in order to eliminate this rejection without in any way affecting the scope of the claims, claim 5 is amended herein to make the change required by the U.S. Patent and Trademark Office.

Claims 5, 43, 44, 46 and 47 were rejected under the enablement requirement of 35 U.S.C. 112, first paragraph.

The arguments presented by the Examiner in connection with this rejection include statements which relate to whether or not the applicants have proven that the present invention would be safe and effective. MPEP section 2107, subsection IV, notes that a rejection based on

asserted "lack of utility," whether grounded upon 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph, rests on the same basis (i.e., an assertion that the disclosed utility is not credible). According to the MPEP, a 35 U.S.C. 112, first paragraph, rejection should be set out as a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. According to the MPEP, a 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a rejection under 35 U.S.C. 112, first paragraph, is to be imposed on "lack of utility" grounds.

Deficiencies under the "useful invention" requirement of 35 U.S.C. 101 can arise in one of two forms. The first is where it is not apparent why the applicant believes the invention to be "useful." This can occur when an applicant fails to identify any specific utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966); In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). Clearly, the present application discloses that the subject matter recited in claim 5, and the claims dependent therefrom, is useful for preventing neoplastic development. The second type of deficiency arises in the rare instance where an assertion of specific utility for the invention made by an applicant is not credible. The statements made by the Examiner do not satisfy the burden for showing that the utility for the claimed invention is not credible, as detailed below. See MPEP, section 2107.

The Examiner attempts to justify this rejection by characterizing the claimed subject matter as being based on speculation (Office Action, page 6, lines 3 and 5). In particular, the Office Action contains a statement that "[t]he specification speculates that anti-serum to snake venom and/or phospholipase A2 are thus active anti-tumor proliferation compounds and immune enhancing" and a statement that "[t]he specification further speculates that anti-serum to phospholipase A2 can be applied as a prophylactic therapy by using phospholipase A2 or synthetic peptides having phospholipase A2 to stimulate an immunoglobulin response within a patient". The Examiner has no basis for asserting that the present specification discloses subject

matter which is based purely on speculation. Rather, the specification contains a description of how to make and use the present invention, as well as some experiments which were interpreted by the present inventor as confirming the mechanism of action of the present invention. The present specification does not characterize the subject matter recited in claims 5, 43, 44, 46 or 47 as being based on speculation.

A rejection cannot be based on the enablement requirement if the Examiner is merely requiring the applicant to "prove" that the invention works as disclosed. Contrary to this principle, the Examiner makes numerous statements which relate to the specification not proving to the Examiner that the invention would work as disclosed. For example, the Examiner states "[i]t is not clear whether Russelli vipera venom entrapped in liposomes and porcine phospholipase A2 entrapped in liposomes could prevent tumor development in mice having leukemia" and "[i]t is possible that the booster vaccines kill the tumor cells . . ." (emphasis added).

A statement by an Examiner that "it is possible" that the invention might not work as disclosed does not satisfy the burden for making a rejection for lack of enablement. As noted in the MPEP, section 2107.01, subsection IV, in order to properly reject a claimed invention under 35 U.S.C. 101, the Office must (A) make a prima facie showing that the claimed invention lacks utility (not merely that the Examiner considers it "possible" that the invention lacks utility), and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the prima facie showing. In re Gaubert, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975). In addition to a statement setting forth a prima facie showing, Office personnel must provide evidentiary support for the prima facie case. According to the MPEP, in most cases, documentary evidence (e.g., articles in scientific journals, or excerpts from patents or scientific treatises) can and should be cited to support factual conclusions made in the prima facie showing. If the Office cannot develop a proper prima facie case and provide evidentiary support for a rejection under 35 U.S.C. 101, a rejection on this ground should not be imposed. See, e.g., In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Rejections under 35 U.S.C. 101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the 35 U.S.C. 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature,

or was wholly inconsistent with contemporary knowledge in the art (See MPEP section 2107.01 III). To assess credibility, the examiner should determine if one of ordinary skill in the art would consider the assertions of the applicant to have any reasonable scientific basis. If they do, they should not be challenged as not being credible.

Furthermore, the Federal Circuit has stated that in order to violate 35 U.S.C. 101, the claimed invention must be totally incapable of achieving a useful result. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992). See also E.I. du Pont De Nemours and Co. v. Berkley and Co., 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity."). Accordingly, in order to satisfy its initial burden for a rejection based on utility, the USPTO must develop a proper prima facie case and provide evidentiary support for its assertion that the invention would be totally incapable of providing any beneficial function (not simply that the Examiner deems that it is possible that the invention might not function as disclosed). Situations where an invention is found to be "inoperative" and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer.

Moreover, it is noted that in order for a compound to be useful as a pharmaceutical, it is not essential that the compound cure any condition, since there are many effects which a pharmaceutical can provide, other than a cure, which are useful.

In addition, it is not incumbent on an applicant to show that an invention would work in every situation, or that it would work on every patient.

The Office Action further contains a statement that "the claims encompass a method for preventing neoplastic development from a normal human, without any tumor. The example in the specification only discloses the inhibition of growth of leukemic cells, or killing of leukemic cells that are injected into mice." This statement does not satisfy the burden on the U.S. Patent and Trademark Office, because it does not provide a prima facie showing that the claimed

invention lacks utility, and it does not provide any evidentiary basis for factual assumptions which could be relied upon in establishing a prima facie showing. In fact, this statement in the Office Action does not even allege that the invention would be incapable of achieving a beneficial result.

The Office Action further contains a statement that "it is unpredictable when and for how long one of skill in the art should administer the claimed phospholipase A2 for preventing cancer development." There is no requirement, in order to satisfy the utility requirement, for the duration of treatment to be predictable. Again, it is respectfully noted that there is no requirement that the present invention achieve any level of effectiveness selected by the Examiner; rather, the invention must not be totally incapable of providing any useful result. Delaying or slowing neoplastic growth to any degree is such a useful result, and the Office Action does not contain a showing that such usefulness cannot be obtained by the present invention.

The Office Action further contains a statement that "if phospolipase A2 is injected continuously during all the life span of human, severe side effects and toxicity could develop and thus preventing the success of the action of phospholipase A2, because several forms of phospholipase A2 are known to be toxic." First of all, as noted above, there is no requirement that the invention be applied for an entire lifetime of a human in order to provide utility. Second, as noted in the MPEP, Office personnel should not construe 35 U.S.C. 101, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans. See MPEP, section 2107. Moreover, it has been consistently and repeatedly recognized that those of skill in the art would avoid activity that would be expected to produce a harmful result. In addition, it is not a function of the claims to specifically exclude possibly inoperative subject matter. Atlas Powder v. E.I. DuPont De Nemours, 224 USPQ 409, 414 (Fed.Cir. 1984); ;Ex parte Janin, 209 USPQ 761, 763 (Pat. Ofc. Bd. App. 1979).

The Office Action further contains a statement that "the specification lacks guidance on dosage, frequency of treatment and assessment of disease progression in human". However, the ability of an artisan skilled in pharmaceutical administration of drugs to determine suitable dosages depending on many inter-related factors is well-known. In addition, as noted above, unless the USPTO can establish that the invention as described would be totally incapable of

producing any useful result, a rejection based on the utility requirement is improper.

The Office Action further contains a statement that "the specification lacks description of how to assess human in risk of developing tumor, e.g., assessment based on family health history and genetic screening of said individual at risk of tumor development." However, as noted above, it is not essential that the invention accomplish all its intended functions or operate under all conditions, or be capable of treating all patients at all times.

The Office Action further contains a statement that "[i]t is unpredictable that phospholipase A2 alone would be able to kill starting tumor cells". As noted above, it is not a requirement for patentability that it would have been "predictable" that the claimed invention would be successful. That is, to make a rejection based on the utility requirement, the USPTO has to make a prima facie showing that the claimed invention lacks utility, and provide an evidentiary basis for factual assumptions relied upon in establishing the prima facie showing. A mere allegation that the degree of efficacy of subject matter within an invention is unpredictable does not satisfy the burden on the USPTO.

The Office Action further contains a statement that "one of skill in the art would not have expected that phospholipase A2 alone could kill or prevent development of tumor mass from starting tumor cells." There is no requirement that those of skill in the art would have expected that the invention would achieve any particular degree of success. Any such requirement would be illogical, given that the present inventor is the first to describe the invention, and so it would be impossible for others of skill in the art to have any expectation as to the efficacy of the invention until the invention becomes known to them.

The Office Action further contains a statement that "In view of the above, undue experimentation would be required to practice the claimed invention." The Office Action contains no allegation that persons of skill in the art would not readily be able to make the invention as claimed. The Office Action contains no allegation that persons of skill in the art would not readily be able to administer the invention. The Examiner's complaint is that it is conceivable that the applicant has not proven that the invention would achieve complete success in all instances. The Examiner's complaints do not provide a basis for an assertion that the present specification lacks an enabling disclosure. Based on the disclosure in the present specification, persons of skill in the art would readily be able to practice the claimed invention, and would expect, as in all inventions, that treatment regimens applied to different patients would

provide varying results. The Examiner has not shown that the invention would be incapable of providing any useful result; the Examiner has merely asserted that it would be her expectation that one would not be able to precisely predict the level of benefits provided to every patient by carrying out every regimen within the scope of the claimed invention.

Reconsideration and withdrawal of this rejection are requested.

Claims 5, 43, 44 and 46-47 were rejected under 35 U.S.C. 112, first paragraph.

The Office Action contains a statement that ". . . the specification . . . does not reasonably provide enablement for a method of preventing neoplastic development comprising administering 'part' of phospholipase A2" because "[i]t would not be possible to determine with any predictability whether the antibodies produced from such fragments actually bind to phospholipase A2". Again, as noted above, there is no requirement that those of skill in the art be able to predict the level efficacy of each embodiment within the invention. The enablement requirement of 35 U.S.C. 112 does not require that an applicant discover and describe which subject matter within a generic group of components function properly in accordance with the invention, and the precise extent of their efficacy. An analogous situation was presented in In re Fuetterer, 138 USPQ 217, 223 (CCPA 1963), in which the USPTO objected to the breadth of certain claims, stating that there would be an undue burden placed upon the public to determine what salts are suitable for obtaining the desired results (the claim recited "an inorganic salt that is capable of . . ."). The CCPA held that there is no requirement that an applicant discover which of all the salts within the generic expression in the claim would function properly in the invention. The court stated that the applicant's claims should not be limited to the salts enumerated in the specification so that they could be avoided merely by using some inorganic salt not named by the applicant in its disclosure. The court stated "the only undue burden which is apparent to us in the instant case is that which the Patent Office has attempted to place on the appellant - the Patent Office would require him to do research on the literally thousands of inorganic salts and determine which of these are suitable for incorporation into his claimed combination." In re Fuetterer, 138 USPQ at 223. The court also stated that "It is clear that the instant claims do not comprehend a class of inorganic salts of any greater breadth than is comprehended by the invention description." In re Fuetterer, 138 USPQ at 223.

The Office Action further contains a statement that the specification provides no working examples. It has repeatedly and consistently been held that there is no requirement that a

specification contain working examples in order to provide enablement. Inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention.

Reconsideration and withdrawal of this rejection are requested.

In view of the above, favorable consideration is solicited.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,
BURR & BROWN

January 2, 2002
Date

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